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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,909	07/25/2007	Alan D. Olstein	21001.012US	7773

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Intellectual Property Dept.
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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
11/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket-ip@dewittross.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,909	OLSTEIN, ALAN D.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 10/6/10 is acknowledged.

Claims 1-13, 15-33 are being examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for "one or more antibiotics that comprise nitrofurantoin". The nature of such antibiotics is not disclosed on this record.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant relies on original claim 2 for support. However, claim 2 recited nitrofuranoin as one antibiotic in a Markush group and not "one or more antibiotics that comprise nitrofurantoin".

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of "one or more antibiotics that comprise nitrofurantoin". The nature of such antibiotics is not disclosed in the instant specification.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Neamatallah *et al.*.

The claims are directed to a growth medium comprising lithium chloride and antibiotics intended for *Listeria.*

Neamatallah *et al.* disclose a growth medium comprising lithium chloride and antibiotics intended for *Listeria.* See, e.g., Table 1.

Therefore, the invention is anticipated by the reference.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant baldly argues that Neamatallah *et al.* does not teach nitrofurantoin in a concentration that is effective to selectively inhibit non-*Listeria* organisms while enhancing growth of *Listeria.* However the claim 1 is not directed to the use of nitrofurantoin as argued, but

rather to the inclusion of one or more antibiotics that comprise nitrofurantoin. Applicant has not set forth such antibiotics or quantities thereof for the alleged functional properties or for any purpose whatsoever in the written disclosure. See, the new matter rejection.

Moreover, the desired functional properties in the rejected claims are not supported by appropriate structure, such as concentration shown to have the alleged functions.

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-13 and 15-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee *et al.* taken with Difco Manual and Neamatallah *et al.*

The claims are directed to a growth medium comprising lithium chloride and antibiotics intended for *Listeria* including nitrofurantoin.

Lee *et al.* disclose a growth medium comprising lithium chloride and antibiotics intended for *Listeria.* See, e.g., page 1215, col. 1, paragraph 2 and col. 3 paragraph 2. The components of phenylethanol agar are disclosed by Difco Manual. See, e.g., page 395. In addition, the Difco Manual adequately demonstrates that the combination of various antibiotics in media for the detection of *Listeria* is old and well known in the art. See, e.g., pages 364-365.

The reference differs from the claimed invention in the addition of nitrofurantoin. However, Neamatallah *et al.* adequately demonstrate that it is known in the art to add nitrofurantoin to selective media intended for the recovery and/or identification of *Listeria.*

Regarding claim 31, all of the ingredients are known in the art to be suitable for selective media for *Listeria* and are provided at art recognized concentrations.

The media discussed in the references appear to be substantially similar as claimed. However, even if they are not, the adjustment of ingredients and concentrations for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" In re Aller, 220 F.2d

454,456, 105 USPQ 233, 235 (CCPA 1955) -MPEP § 2144.05.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition of Lee *et al.* by adding nitrofurantoin as an additional selective tool, for the expected benefit of better selecting and identifying the dangerous pathogen *Listeria.*

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's arguments regarding sensitivity to nitrofurantoin by *Listeria* are noted. However, there is no claim designated concentration in the rejected claims, except for dependent claims 7-8 and claim 31. The functional limitations constitute desired results. Yet the functional limitations are not supported by structure such as concentrations in most of the claims. Moreover, applicant has not shown on this record that all strains of *Listeria* are resistant to nitrofurantoin in concentrations "from about 0.001 g/l to about 0.01 g/l or even of about 0.006 g/l as contended. Neamatallah *et al.* use a concentration of 50 μg nitrofurantoin, but did not indicate whether it is per liter or per ml. Thus, the concentrations cannot be readily compared or assessed as to effects

Regarding claim 9, the fact that the Difco Manual includes acriflavin does not readily distinguish over a claim wherein the medium is "substantially devoid" of this compound, since this terminology is not defined in the specification as to is meaning. On the contrary, only in a preferred embodiment is no acriflavin present [0012]. Therefore, this argument is without merit.

Regarding the combinations of various antibiotics as recited in Claim 15 very broadly, even though the prior art does not specifically include the recited antibiotics, there is nothing in the claim regarding concentrations, for example. Therefore, the significance of the addition of further antibiotics has not been substantiated on this record.

Applicant's arguments regarding claim 31 are noted including the statements regarding what applicant considers to be the closest prior art medium, i.e., Oxford Medium Base with the Oxford supplement as well as the differences. It is reiterated that all of the ingredients are

known in the art to be suitable for selective media for *Listeria* and are provided at art recognized concentrations. The nature of compared medium is uncertain.

Moreover, Applicant fails to consider that in claim 31 all the concentrations are recited to include the term "about" for every single component. Thus, the amounts included are variable and the material in the written disclosure provides no evidence regarding the unobviousness of the medium as claimed with respect to the growth of any and all *Listeria* for the amounts as claimed designated. The medium PDX-2 resembles the medium of claim 33, except that in claim 33 the medium is "substantially devoid" rather than free of acriflavin and in the recitation of "about" for any and all components. Even for medium PDX-2, Table 4 shows that *Listeria grayi* and *Listeria seelgreri* failed to grow. Therefore, the scope of even this claim is not commensurate with the showing in the specification.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore applicant has not overcome the strong *prima facie* case of obviousness and the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner